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10/532,447	04/22/2005	Aldo Pinchera	B-0496 PUS	1713

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EXAMINER	
KLINKEL, KORTNEY L	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,447	PINCHERA ET AL.	
	Examiner	Art Unit	
	Kortney L. Klinkel	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15 and 17-25* is/are pending in the application.

4a) Of the above claim(s) *17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the remarks/amendments filed 12/13/2010. Claims 1-8 and 16 stand canceled. Claims 9-15 and 17-25 are pending. Claims 9, 14, 17, and 20 were amended. Claims 17-24 remain withdrawn for being directed to a non-elected invention. Claims 9-15 and 25 are under consideration in the instant Office action.

Miscellaneous

It is noted that claim withdrawn claim 17, which is currently amended, is missing the article "A" at the beginning of the claim. This change has not been noted via the proper amendment markings as required by 37 CFR 1.121. It is thought that the article "A" has been deleted inadvertently. Appropriate corrective action is requested.

Claim Rejections - 35 USC § 102—Withdrawn

The rejection of claims 9-10, 12 under 35 U.S.C. 102(b) as being anticipated by Chopra et al. ("Demonstration of Thyromimetic Effects of 3,5,3'-Triiodothyronine Sulfate (T_3S) in Euthyroid Rats" Thyroid, 1996, 6(3), 229-232, as per Applicant's IDS dated 4/22/2005) is withdrawn in light of the claim amendments to require that the dosage form be in solid form.

Claim Rejections - 35 USC § 103—Withdrawn

The rejection of claims 11 and 13 under 35 U.S.C. 103(a) as being unpatentable over Chopra et al. ("Demonstration of Thyromimetic Effects of 3,5,3'-Triiodothyronine

Sulfate (T_3S) in Euthyroid Rats" Thyroid, 1996, 6(3), 229-232, as per Applicant's IDS dated 4/22/2005) in view of Miura et al. (US 5116828; of record) is withdrawn in light of the claim amendments.

The rejection of claims 14-15 and 25 under 35 U.S.C. 103(a) as being unpatentable over Chopra et al. ("Demonstration of Thyromimetic Effects of 3,5,3'-Triiodothyronine Sulfate (T_3S) in Euthyroid Rats" Thyroid, 1996, 6(3), 229-232, as per Applicant's IDS dated 4/22/2005) in view of Miura et al. (US 5116828; of record) in further view of Chiang et al. (US 2001/0051657) is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra et al. ("Demonstration of Thyromimetic Effects of 3,5,3'-Triiodothyronine Sulfate (T_3S) in Euthyroid Rats" Thyroid, 1996, 6(3), 229-232, as per Applicant's IDS dated 4/22/2005) in view of Miura et al. (US 5116828; of record) and Remington: The Science and Practice of Pharmacy, 19th edition, 1995, Alfonso R. Gennaro, Ed., Chapter 92, Oral Solid Dosage Forms by Edward Rudnic, PhD, pages 1615-1649, referred to hereafter as "Remington").

Chopra et al. teach a liquid composition comprising triiodothyronine sulfate (T_3S) in a dose of 3.5 μg, 10.5 μg and 31.5 μg (p. 230, Experimental procedures). Note that the dosage amount of 31.5 μg falls within the claimed dosage ranges required by the claims. These liquid compositions comprising T_3S are administered to rats via injection (p. 230, Experimental procedures). The liquid composition when administered *in vivo* to rats leads to no ill effects (see data Table 1, also Results). As the composition is in liquid form, it necessarily comprises a carrier.

Additionally, Chopra et al. teach that T_3S exhibits thyromimetic effects in hypothyroid rats and that on a molecular basis it is approximately one fifth (20%) as active as triiodothyronine (T_3) (p. 229, Introduction second full paragraph, also abstract). Chopra et al. teach that adult and fetal tissues contain sulfatase(s) which are capable of converting T_3S into T_3 (p. 230 final two sentences through p. 231 end of first partial paragraph). The thyromimetic effects of T_3S, which are observed in both euthyroid rats and in hypothyroid rats, is likely due to the generation of T_3 in tissues by desulfation of T_3S (abstract, p. 231 first column). T_3S exhibits the same potency as T_4 (thyroxine), which is also a source of T_3 (p. 231, first paragraph and first paragraph p. 229). The potency of both T_3S and T_4 is 20% of that of T_3. Chopra et al. also teach that treatments of T_3 and T_3S both caused a significant reduction in serum T_4 and TSH levels (abstract, Results p. 230).

The teachings of Chopra et al. differ from the instant claims in that the composition of Chopra et al. is a liquid rather than a solid. The teachings of Chopra et al. also differ from instant claims 11 and 13 in that the composition of Chopra et al. does not contain the requisite ingredient T_4 (thyroxine). These deficiencies are cured by the teachings of Miura et al. and Remington.

Miura et al. teach L-thyroxine (T_4) in oral doses of 25-400 µg/day, and L-triiodothyronine (T_3) in oral doses of 5-150 µg/day (col. 3, lines 1-4). These doses can be formulated as solid oral dosage forms or as liquids for parenteral administration and can contain common excipients, binders, disintegrators, lubricants, thickeners, wetting agents, buffers, solvents, oils, among others (col. 6, lines2-26). See also the table in

column 6, lines 37-50 which shows solid oral dosage forms of T_4 and T_3 in the form of a tablet and capsule respectively containing Lactose, *inter alia*. Miura et al. also teach that T_4 and T_3 are thyroid hormones (col. 3, lines 1-6, claim 2).

Remington teaches that drugs are most frequently administered by solid oral dosage forms (p. 1615, introduction). Tablets offer several advantages including simplicity and economy of preparation, stability and convenience in packaging, shipping and dispensing. Tablets also offer advantages to the patient including accuracy of dosage, compactness, portability, blandness of taste and ease of administration (p.1615). Capsules also offer several benefits including the fact that they are tasteless, easy to administer and are easily filled. Capsules also allow two drugs to be formulated together in the exact dosage level considered best for the individual patient, which is an advantage over tablets (p. 1642). Remington also teaches that solid oral formulations more often than not contain additives or excipients in order to improve stability and aid in delivery of the drug to the bloodstream after administration (p. 1615 and pp. 1617-1621).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have formulated T_3S as a solid oral dosage form suitable for human use with a reasonable expectation for success. Both T_3S and T_4 produce the more active thyroid hormone T_3 in vivo. T_3S and T_4 both also exhibit thyromimetic effects; effects which are about 20% as potent at T_3. Stated another way, T_3S T_3 and T_4 are also known to exhibit thyromimetic effects and are thereby functional equivalents. One would be motivated to formulate T_3S as a solid oral dosage form given the fact that the

functional equivalents T_3 and T_4 have both been successfully formulated as solid oral dosage forms. Further motivation to formulate T_3S as a solid oral dosage form stems from the fact that solid oral dosage forms offer several advantages including the fact that they are easy to prepare, offer stability to the drug and lead to higher patient compliance given the fact that they offer an accurate dose, are compact, portable and easy to administer. A patient can administer a solid oral dosage form themselves and do not need the help of a healthcare professional to inject the requisite drug.

Regarding claims 11 and 13 which require the additional ingredient thyroxine (T_4), it would have been obvious to one of ordinary skill in the art at the time of the instant invention to construct a solid oral dosage form suitable for human use comprising both T_3S in an amount from 5 to 1000 μg, or most specifically from 25 to 250 μg, as well as T_4 in an amount of 10 to 250 μg, or most specifically 25 to 200 μg with the reasonable expectation that such a composition would have thyromimetic effects. One would have been motivated to do so because both T_3S and T_4 produce the more active thyroid hormone T_3 in vivo. Both T_3S and T_4 are also known to exhibit thyromimetic effects. By these tokens they are functional equivalents. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). In the instant situation one of ordinary skill in the art would be imbued with the reasonable expectation that the combination of one

thyromimetic with another would, when combined, result in a third composition also capable of exhibiting thyromimetic effects and in this case also producing the thyroid hormone T_3 upon administration. One would be particularly motivated to add T_4 to the composition containing T_3S since it is known that the administration of T_3S leads to low serum levels of T_4. One would add T_4 in an effort to give the patient an opportunity to round out their thyroid hormone levels. One would be motivated to use 25 to 200 μg of T_4 because the prior art teaches that daily dosages of 25-400 μg are common dosages. This dosage range overlaps with the claimed dosage amounts. It is also well known in the pharmaceutical arts to adjust the relative dosage depending on the subject to be administered, the preparation form, route for administration etc. (Miura et al. col. 2, lines 32-44). As taught by Remington, the solid oral dosage form, capsules, allow two drugs to be formulated together if desired and the exact dosage level considered best for the individual patient can be easily formulated. This is another facet of motivation as to why one would desire formulating T_3S and T_4 in solid form.

Claims 14-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra et al. ("Demonstration of Thyromimetic Effects of 3,5,3'-Triiodothyronine Sulfate (T_3S) in Euthyroid Rats" Thyroid, 1996, 6(3), 229-232, as per Applicant's IDS dated 4/22/2005) in view of Miura et al. (US 5116828; of record) and Remington: The Science and Practice of Pharmacy, 19th edition, 1995, Alfonso R. Gennaro, Ed., Chapter 92, Oral Solid Dosage Forms by Edward Rudnic, PhD, pages 1615-1649,

referred to hereafter as "Remington") in further view of Chiang et al. (US 2001/0051657).

The teachings of Chopra et al., Miura et al. and Remington are set forth above. The combined teachings of Chopra et al. Miura et al. and Remington fail to teach a kit as required by claims 14-15 and 25.

Chiang et al. teach kits useful for treating a variety of conditions including hypothyroidism comprising two different pharmaceutical compositions each useful at treating hypothyroidism as well as a container ([0139]-[0142]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have developed a kit comprising a solid oral composition comprising T_3S and a second composition comprising T_4 in a solid oral dosage, more specifically wherein the respective compositions comprise from 10 to 500 μg or 25 to 250 μg T_3S and from 10 to 250 μg or 25 to 200 μg T_4. One would have been motivated to do so because kits comprising two different compositions for treating the same condition, including hypothyroidism, which both T_3S and T_4 are known to do, are well known in the prior art. One would be particularly motivated to add a second composition comprising T_4 since it is known that the administration of T_3S leads to low serum levels of T_4. One would add a T_4 composition to the kit in an effort to give the patient an opportunity to round out their thyroid hormone levels.

Response to arguments

Applicant's arguments filed 12/13/2010 regarding the rejection of claims have been fully considered, but are moot in light of the new grounds of rejection. The new grounds of rejection, necessitated by amendment, teach all the claim limitations. However, in an effort to expedite prosecution, the Examiner will address any issues still relevant.

Applicant argues that it is well known that both i.p. and i.v. administration drive a drug or prodrug such as T_3S directly into the bloodstream and from the bloodstream to peripheral tissues and organs and that therefore i.p. and i.v. routes are more direct and more efficient at conveying an active drug to peripheral tissues. Applicant cites Goodman & Gilman's The Pharmacological Basis of Therapeutics (see page 6 of the response). It is noted that a copy of this document was not provided. Applicant concludes that the skilled artisan could not expect oral administration to have the same efficiency as observed by the i.p. route, thus pointing to the non-obviousness of the claimed solid oral compositions of T_3S. This argument is not persuasive.

The above argument hinges on features which are not required by the claims. The claims do not set forth a level of efficiency of delivery of T_3S, but merely require T_3S to be formulated in a solid oral dosage form suitable for human use. The teachings of the prior art suggest several reasons as to why one would be motivated to formulate T_3S in a solid oral dosage form. These reasons include the fact that functional equivalents T_3 and T_4 have both been successfully formulated as solid oral dosage forms. Further motivation to formulate T_3S as a solid oral dosage form stems from the fact that solid oral dosage forms offer several advantages including the fact that they

are easy to prepare, offer stability to the drug and lead to higher patient compliance given the fact that they offer an accurate dose, are compact, portable and easy to administer. A patient can administer a solid oral dosage form themselves and do not need the help of a healthcare professional to inject the requisite drug.

Applicant argues that Chopra teaches that T_3S is mainly converted to T_3 in the peripheral tissues and that the conversion has an overall low efficiency and only achieves about 1/5 of the potency as achieved with T_3. Applicant argues that given this inefficient conversion observed by i.p. injection, the skilled artisan would not have been motivated to prepare or expect success from formulating T_3S in a solid composition for oral administration. Applicant argues that the skilled artisan would have expected that oral administration would have resulted in an additionally limiting factor of a low drug permeation rate through the GI tract to the peripheral tissues for the enzymatic conversion to T_3 which would further delay and potentially interfere with an already inefficient T_3S to T_3 conversion process. Applicant concludes that Chopra neither teaches nor suggests the claimed solid T_3S composition. These arguments are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Chopra et al. in view of Miura and Remington teach all the limitations of the instant claims. It is also noted that applicant has not provided

evidence of unexpected results for the claimed composition. Furthermore, it is noted that the art recognizes the fact that T_3S is only about $1/5^{th}$ as potent as T_3. It is also known that T_3S is known to be converted to the active T_3 upon in vivo administration due to the presence of sulfatases in adult and fetal tissues (Chopra, Discussion p. 230).

Regarding the argument that the skilled artisan would have expected that oral administration would have resulted in an additionally limiting factor of a low drug permeation rate through the GI tract to the peripheral tissues for the enzymatic conversion to T_3 which would further delay and potentially interfere with an already inefficient T_3S to T_3 conversion process, it is noted that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(b). As discussed in the above rejection, Remington teaches that additives are added to solid oral dosage forms in order to improve bioavailability. The state of the prior art is such that one of ordinary skill in the art would be imbued with the reasonable expectation that a solid oral dosage form of T_3S would exhibit bioavailability upon administration. Applicant has not provided objective evidence to the contrary.

Applicant argues that the claimed oral compositions have unexpected advantages over the cited references. Specifically applicant argues that the claimed

invention is significantly easier to administer and more convenient than the i.p. compositions of Chopra. This argument has been fully considered, but is not persuasive. The prior art applied in the instant rejections suggests that oral compositions are expected to be easier to administer and more convenient. "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). See also MPEP 716.02(c) II.

On page 8 of the arguments applicant argues three points as to why one of ordinary skill in the art would not have expected a therapeutic effect upon oral administration of T_3S. These points in summary are 1) that oral administration is less predictable and results in less rapid availability than parenteral administration and that the same composition, once administered orally can't be expected to provide the same results as observed by a different administration route, 2) T_3S is a highly polar molecule and since very low oral adsorption rates are usually expected for polar molecues, T_3S would not have been expected to efficiently cross the GI system, and 3) Lopresti taught that T_3S is an inactive metabolite with no detectable biological activity that is poorly absorbed from the GI tract. These arguments are not persuasive.

Regarding point 1), it is noted that applicant's claims are directed to a composition and not a method of use. Further, the argument hinges on features not instantly claimed. There is no requirement that the oral solid dosage form provide the same results as observed by a different administration route. Accordingly this argument is unpersuasive.

Regarding point 2), this argument is not supported by fact that arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(b).

Regarding point 3), this argument is based on the teachings of Lopresti. The rejection over Lopresti was withdrawn in the Office action dated 10/22/2009. This fact was also pointed out in the previous Office action. Applicant is requested to keep their arguments poignant to the pending rejections and not rejections which have been withdrawn. As addressed in the previous Office action, the rejection over Lopresti was withdrawn because one would not have been motivated to administer the instant claim's required dose of radiolabeled T_3S without inflicting undue harm to the subject. Again it is noted that the amount of radiolabeled T_3S is far smaller than the amount required by the instant claims or the amount administered in the currently applied prior art. Only 25 μCi of radiolabeled T_3S is administered (p. 704, second column, second to final full paragraph).[1] Accordingly, based on the dosage amount alone, one would not expect this small amount of radiolabeled T_3S to have an effect given the state of the prior art.

[1] Given the fact that ^{125}I has a specific radioactivity of 75 GBq/μmol and 1 Ci = 3.7×10^{10} Bq and the molecular weight of T_3S of 729 g/mol, one can calculate that only 0.009 μg of radiolabeled T_3S was administered in Lopresti.

The composition administered by Lopresti orally is also a liquid formulation and not a solid formulation as instantly claimed. Furthermore, Lopresti, published 1991, is not considered to be the state of the prior art, nor the closest prior art relevant to the instant claims. Chopra et al., applied in the above rejections, was published in 1996 and notes that it seemed possible that T_3S is active only in hypothyroidism and not in the euthyroid state wherein normal tissue 5'-DI activity will rapidly degrade T_3S and little T_3S will be left for metabolism to biologically active T_3 (abstract). However, the study by Chopra et al. shows that T_3S exhibits thyromimetic effects in euthyroid rats comparable to that in hypothyroid rats (abstract).

Again applicant argues that their compositions exhibit unexpected results and point to the declaration of Dr. Pinchera, filed with a previous response on April 9, 2010. Applicant argues that the data shows that the oral compositions were absorbed by the GI system and metabolized to the active T_3 when administered to humans at doses of 20-160 micrograms of T_3S. Applicant argues that this data is unexpected given the inefficient conversion of T_3S to T_3 observed in Chopra using the more efficient i.p. administration and given the polar nature of T_3S and the teachings of Lopresti that oral radiolabeled T_3S was inactive and presumably not absorbed by the GI tract and in view of the large dosages of T_3S of 2930 micrograms of Santini for i.p. administration. These arguments are unpersuasive.

Again is it noted that Lopresti is no longer of record, nor is Santini. The declaration of Dr. Pinchera was addressed by the Examiner in the previous Office action. Furthermore as discussed above, the fact that T_3S is absorbed by the GI

system and metabolized to active T_3 is not unexpected given the applied references. There is nothing of record suggesting that T_3S would not be bioavailable upon oral administration. The prior art applied in the instant rejections suggests that solid oral compositions of T_3S alone and/or together with T_4 would be expected to be bioavailable. "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). See also MPEP 716.02(c) II.

Conclusion

Claims 9-15 and 25 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 10 am to 7 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Ashwin Mehta/
Primary Examiner, Art Unit 1638